

Claims

What is claimed is:

1. A capsule comprising a fenofibrate composition, said fenofibrate composition comprising fenofibrate, at least one hydrophilic polymer and at least one disintegrating agent,
5 wherein the weight ratio of fenofibrate to hydrophilic polymer is between 1:10 and 4:1.
2. The capsule according to claim 1, wherein the weight ratio of fenofibrate/hydrophilic polymer is between 1/2 and 2/1.
3. The capsule according to claim 1, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose,
10 hydroxypropylmethylcellulose, gelatin, or a mixture of two or more thereof.
4. The capsule according to claim 1, wherein the hydrophilic polymer is polyvinylpyrrolidone.
5. The capsule according to claim 1, wherein the hydrophilic polymer is hydroxypropylcellulose.
- 15 6. The capsule according to claim 1, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.
7. The capsule according to claim 1, having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the
20 rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.
8. The capsule according to claim 1, wherein the fenofibrate is present in an amount of 5 to 50% by weight.
- 25 9. The capsule according to claim 1, wherein the fenofibrate is present in an amount of 20 to 45% by weight.
10. The capsule according to claim 1, wherein the fenofibrate is in a non-reagglomerated form.
11. A capsule comprising a fenofibrate composition, said fenofibrate composition /
30 comprising fenofibrate, polyvinylpyrrolidone and at least one disintegrating agent, wherein the weight ratio of fenofibrate to polyvinylpyrrolidone is between 1:10 and 4:1.

12. The capsule according to claim 11, wherein the weight ratio of fenofibrate/polyvinylpyrrolidone is between 1/2 and 2/1.

13. The capsule according to claim 11, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

14. The capsule according to claim 11, having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

15. The capsule according to claim 11, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

16. The capsule according to claim 11, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

17. The capsule according to claim 11, wherein the fenofibrate is in a non-reagglomerated form.

18. A capsule comprising a fenofibrate composition, said fenofibrate composition comprising fenofibrate, hydroxypropylcellulose and at least one disintegrating agent, wherein the weight ratio of fenofibrate to hydroxypropylcellulose is between 1:10 and 4:1.

19. The capsule according to claim 18, wherein the weight ratio of fenofibrate/hydroxypropylcellulose is between 1/2 and 2/1.

20. The capsule according to claim 18, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

21. The capsule according to claim 18, having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

22. The capsule according to claim 18, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

23. The capsule according to claim 18, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

24. The capsule according to claim 18, wherein the fenofibrate is in a non-reagglomerated form.

25. A capsule comprising a fenofibrate composition, said fenofibrate composition comprising fenofibrate, at least one hydrophilic polymer and at least one disintegrating agent, wherein the weight ratio of fenofibrate to hydrophilic polymer is between 1:10 and 4:1, and having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

26. The capsule according to claim 25, wherein the weight ratio of fenofibrate/hydrophilic polymer is between 1/2 and 2/1.

27. The capsule according to claim 25, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture of two or more thereof.

28. The capsule according to claim 25, wherein the hydrophilic polymer is polyvinylpyrrolidone.

29. The capsule according to claim 25, wherein the hydrophilic polymer is hydroxypropylcellulose.

30. The capsule according to claim 25, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

31. The capsule according to claim 25, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

32. The capsule according to claim 25, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

33. The capsule according to claim 25, wherein the fenofibrate is in a non-reagglomerated form.

34. A capsule comprising a fenofibrate composition, said fenofibrate composition comprising fenofibrate, polyvinylpyrrolidone and at least one disintegrating agent, wherein the weight ratio of fenofibrate to polyvinylpyrrolidone is between 1:10 and 4:1, and having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

35. The capsule according to claim 34, wherein the weight ratio of fenofibrate/polyvinylpyrrolidone is between 1/2 and 2/1.

36. The capsule according to claim 34, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

37. The capsule according to claim 34, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

38. The capsule according to claim 34, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

39. The capsule according to claim 34, wherein the fenofibrate is in a non-reagglomerated form.

40. A capsule comprising a fenofibrate composition, said fenofibrate composition comprising fenofibrate, hydroxypropylcellulose and at least one disintegrating agent, wherein the weight ratio of fenofibrate to hydroxypropylcellulose is between 1:10 and 4:1, and having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

41. The capsule according to claim 40, wherein the weight ratio of fenofibrate/hydroxypropylcellulose is between 1/2 and 2/1.

42. The capsule according to claim 40, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

43. The capsule according to claim 40, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

44. The capsule according to claim 40, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

5 45. The capsule according to claim 40, wherein the fenofibrate is in a non-reagglomerated form.